

REMARKS

With this response, claims 1, 2, 5, 7, 10, and 122-145 are pending.

The present invention relates to certain novel 3-cyanoquinoline, 3-cyano-1,6-naphthyridine and 3-cyano-1,7-naphthyridine containing compounds as well as their pharmaceutically acceptable salts.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1-4 were rejected under 35 U.S.C. § 112, First Paragraph, as failing to comply with the enablement requirement (paper no./Mail Date 20050510, page 2).

Applicants respectfully traverse the Examiner's grounds for rejection of claims 122-145 for the reasons which follow.

The Examiner cited *Ex parte Foreman*, 230 USPQ at 547 and *In re Wands*, 858 F2d 7731, USPQ 2d 1400, Fed. Cir. 1988, stating that "[t]he claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention.

In response, there are no *per se* rules of unpatentability and, in particular, each case of enablement "must be determined on its own facts." *In re Angstadt*, 190 USPQ at 218. In the current case the specification describes how to make the claimed compounds in Schemes 1 - 20, on pages 98 – 121. On pages 121 – 124 of the specification the standard pharmacological test procedure used to test the claimed compounds is given.

The Examiner's attention is directed to *US v Telectronics Inc.*, 8 USPQ2d 1217, 1222, 1223 (Fed. Cir. 1988), where it was stated

"A patent may be enabling even though  
some experimentation is necessary; ..."

\* \* \*

"[t]he law does not require an applicant to  
describe in his specification every  
conceivable embodiment of the invention;  
*Hybritech Inc.*, 802 F2d at 1384, 231 USPQ  
at 94 (the enablement requirement may be

satisfied even though some experimentation is required).”

The rejection fails to provide a *prima facie* case by providing reasons why given 20 Schemes for making the claimed compounds, a method for testing said compounds for the claimed utilities, and 567 working examples a person skilled in the art at the time the application was filed would not recognize in the disclosure a description of the invention defined by the claims (M.P.E.P. 2163.04, Rev. 2 May 2004). For this reason this application is enabling and the rejection should be withdrawn.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1, 5, 10, and 122-145 were rejected under 35 U.S.C. § 112, Second Paragraph, as being indefinite (paper no./Mail Date 20050510, page 4).

With a view toward furthering prosecution claims have been amended as follows.

Claims 5, 8-9, 124-136, 139-141, and 143-144 have been canceled.

In claims 1, 122, 137, 138, 142, and 145 the proviso for the values of variables T and Z have been removed.

In claims 1, 122, 137, 138, 142, and 145 the language, “or particularly 1 or 2 heteroatoms which may be same or different, selected from N, O and S” has been removed.

The term neoplasm is defined in the specification on pages 72 and 80 as, “[s]uch neoplasms include those of the breast, kidney, bladder, mouth, larynx, esophagus, stomach, colon, ovary, lung, pancreas, skin, liver, prostate or brain.”. The definition of neoplasm is commonly used by one of skill in the art and is defined in the 27<sup>th</sup> edition of Dorland’s Illustrated Medical Dictionary, 1988, W. B. Saunders Company, Philadelphia, PA, page 1105, as, “any new and abnormal growth; specifically a new growth of tissue in which the growth is uncontrolled and progressive.”

In claims 137 and 138 the term used was “polycystic kidney disease” a specific kidney disease known by one of skill in the art.

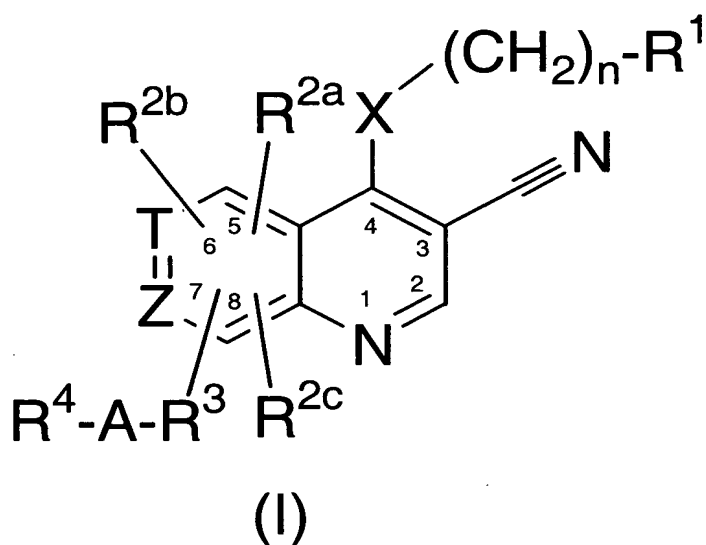
In view of these amendments, the rejection of claims 1, 5, 10, and 122-145 is rendered moot. Accordingly, withdrawal of the rejections is requested.

Rejection Under 35 U.S.C. § 103 (a)

Claims 1, 2, 5, 7, 10 and 122-145 were rejected under 35 U.S.C. § 103 (a), as being obvious over Wissner U. S. Patent No. 6,355,636 (the '636 patent) (paper no./Mail Date 20050510, page 6).

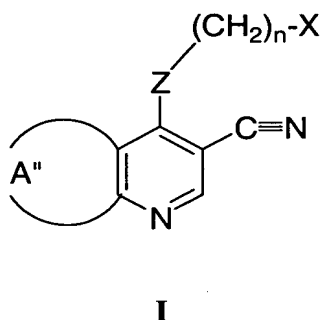
Applicants respectfully traverse the Examiner's grounds for rejection of claims 1, 2, 5, 7, 10, and 122-145 for the reasons which follow.

The compounds of the current application have a core structure

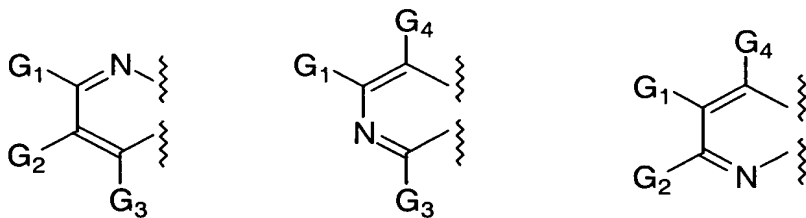


T is C and Z is N and A is cycloalkyl, ~~provided that both T and Z are not simultaneously N;~~

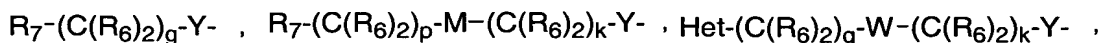
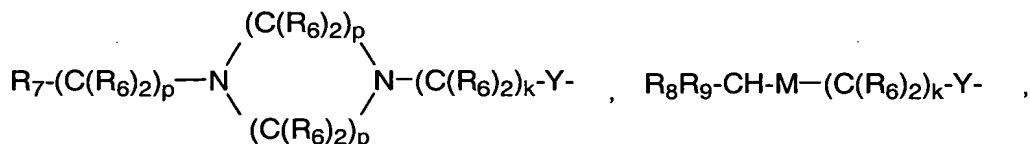
The compounds of the '636 patent have a core structure



A'' is a divalent moiety selected from the group

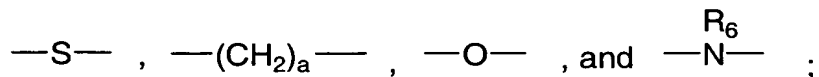


G<sub>1</sub>, G<sub>2</sub>, G<sub>3</sub>, and G<sub>4</sub> are each, independently, hydrogen, halogen, alkyl of 1-6 carbon atoms, alkenyl of 2-6 carbon atoms, alkynyl of 2-6 carbon atoms, alkenyloxy of 2-6 carbon atoms, alkynyloxy of 2-6 carbon atoms, hydroxymethyl, halomethyl, alkanoyloxy of 2-6 carbon atoms, alkenoyloxy of 3-8 carbon atoms, alkynoyloxy of 3-8 carbon atoms, alkanoyloxymethyl of 2-7 carbon atoms, alkenoyloxymethyl of 4-9 carbon atoms, alkynoyloxymethyl of 4-9 carbon atoms, alkoxymethyl of 2-7 carbon atoms, alkoxy of 1-6 carbon atoms, alkylthio of 1-6 carbon atoms, alkylsulphinyl of 1-6 carbon atoms, alkylsulphonyl of 1-6 carbon atoms, alkylsulfonamido of 1-6 carbon atoms, alkenylsulfonamido of 2-6 carbon atoms, alkynylsulfonamido of 2-6 carbon atoms, hydroxy, trifluoromethyl, trifluoromethoxy, cyano, nitro, carboxy, carboalkoxy of 2-7 carbon atoms, carboalkyl of 2-7 carbon atoms, phenoxy, phenyl, thiophenoxy, benzyl, amino, hydroxyamino, alkoxyamino of 1-4 carbon atoms, alkylamino of 1-6 carbon atoms, dialkylamino of 2 to 12 carbon atoms, N-alkylcarbamoyle, N,N-dialkylcarbamoyle, N-alkyl-N-alkenylamino of 4 to 12 carbon atoms, N,N-dialkenylamino of 6-12 carbon atoms, phenylamino, benzylamino, R<sub>2</sub>NH,



with the proviso that G<sub>3</sub> and G<sub>4</sub> are not R<sub>2</sub>NH;

Y is a divalent radical selected from the group consisting of



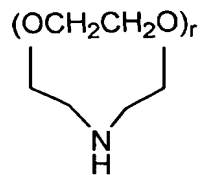
R<sub>7</sub> is -NR<sub>6</sub>R<sub>6</sub>, -OR<sub>6</sub>, -J, -N(R<sub>6</sub>)<sub>3</sub><sup>+</sup>, or -NR<sub>6</sub>(OR<sub>6</sub>);

M is >NR<sub>6</sub>, -O-, >N-(C(R<sub>6</sub>)<sub>2</sub>)<sub>p</sub>NR<sub>6</sub>R<sub>6</sub>, or >N-(C(R<sub>6</sub>)<sub>2</sub>)<sub>p</sub>-OR<sub>6</sub>;

W is >NR<sub>6</sub>, -O- or is a bond;

Het is a heterocyclic radical selected from the group consisting of morpholine, thiomorpholine, thiomorpholine S-oxide, thiomorpholine S,S-dioxide, piperidine,

pyrrolidine, aziridine, pyridine, imidazole, 1,2,3-triazole, 1,2,4-triazole, thiazole, thiazolidine, tetrazole, piperazine, furan, thiophene, tetrahydrothiophene,



tetrahydrofuran, dioxane, 1,3-dioxolane, tetrahydropyran, and ;

Because the '636 patent does not disclose a cycloalkyl substitution on A", the compounds of the current application are not obvious.

It is believed that for the reasons stated above the present application is in condition for allowance and respectfully request that the Examiner allow the application.

A transmittal and a Petition for Extension of Time is attached.

  
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